## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL ACTIONS

Civil Action No. 1:19-md-2875

Honorable Renée Marie Bumb District Judge

## ORDER AS TO PRODUCTION OF LOSARTAN AND IRBESARTAN STRUCTURED DATA FROM PHARMACY DEFENDANTS

WHEREAS, in Case Management Order 32 ("CMO 32") on April 21, 2023, the Court ordered that Defendants Albertson's LLC, CVS Pharmacy, Inc., Express Scripts, Inc., Humana Pharmacy, Inc., Kroger Co., OptumRx, Inc., Optum, Inc., Rite Aid Corp., Walgreen Co., and Walmart Inc. (collectively, the "Pharmacy Defendants") "shall provide to plaintiffs ... [certain] information relating to class certification claims," including "previously-redacted retailer identifiers of [Economic Loss Class] members," namely, Protected Health Information ("PHI") as related to Valsartan (Doc. 2343, section 6.1.3);

WHEREAS, the Pharmacy Defendants previously produced in this case structured dispensing data containing information about each Pharmacy Defendant's dispensing of valsartan-containing drugs ("Valsartan Structured Data");

WHEREAS, within that Valsartan Structured Data, each Pharmacy Defendant originally redacted, anonymized, or withheld from the production of that Structured Data certain fields of information containing PHI, as that phrase is defined in the Health Insurance Portability and Accessibility Act of 1996, Pub. L. 104-191 and regulations promulgated thereunder, belonging to the individuals corresponding to each line of data ("Previously Redacted or Withheld Information");

WHEREAS, on June 20, 2023, following class certification of valsartan-related claims, the Court issued "Amended Order re CMO 32" requiring the production of PHI as the minimum necessary disclosure for the purposes of providing litigation class notice and administration for the certified valsartan classes (Doc. 2434);

**WHEREAS,** on November 20, 2023, the Court entered CMO 35 as to discovery on the losartan and irbesartan cases and set deadlines for the production of documents (Doc. 2538);

WHEREAS, counsel for Plaintiffs and Pharmacy Defendants have met and conferred to determine, consistent with the Court's earlier valsartan order(s), what limited losartan and irbesartan structured data ("Losartan and Irbesartan Structured Data") should be provided, and what would trigger a requirement of Pharmacy Defendants, to produce the PHI associated with such data to satisfy such orders.

WHEREAS, the parties came to an agreement that the Losartan and Irbesartan Structured Data shall be produced, subject to the issuance of a valid subpoena, on or before July 8, 2024, and that the production of PHI consistent with prior orders, shall be triggered upon either (1) the certification of a litigation class action involving consumers and/or Third Party Payors ("TPPs") of Losartan or Irbesartan Containing Drugs ("LCD"s or "ICD"s) and a court order is issued requiring the production of PHI listed in subsections (c) and (d) of the subpoena as the minimum necessary disclosure for purposes of the litigation, or (2) announcement of a settlement or partial settlement in the MDL involving consumers and/or TPPs of LCDs and/or ICDs, accompanied by issuance of a court order requiring the production of PHI in subsections (c) and (d) as the minimum necessary disclosure for purposes of that settlement.

<sup>&</sup>lt;sup>1</sup> As set forth in Attachment B to the subpoena for structured data, subsection (c) requires the production of "the name, date of birth, mailing address, e-mail address(es) and phone number(s) for each consumer or patient identified in subsection (a) and (b)." Subsection (d) requires the "amount paid by TPPs...for LCDs or ICDs dispensed by you identified in subsection (a) and the identity of those TPPs."

WHEREAS, on April 8, 2024, Plaintiffs issued a subpoena to CVS Pharmacy, Inc., Walmart Inc., Walgreen Co., Express Scripts, Inc., Humana Pharmacy, Inc., Optum, Inc., OptumRx, Inc., The Kroger Co., and Albertson Companies, LLC through their counsel of record.

WHEREAS, a partial settlement has been reached in this case on behalf of consumers and TPPs as to ICDs manufactured by Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC ("Aurobindo") requiring the production, for the purposes of class notice and administration, of certain PHI related to those specific ICDs.

WHEREAS, the Court previously found good cause to enter an Amended Confidentiality and Protective Order (Doc. 1661, "Protective Order") to protect "PROTECTED INFORMATION," including personal psychiatric, psychological, employment, and/or medical information, and/or other highly sensitive information and to restrict the use of such information for only those purposes enumerated in the Protective Order;

WHEREAS, the Court specified in the Protective Order that the production of PHI be designated as "Restricted Confidential" and shall not, without leave of this Court, be disclosed to any person or entity other than those specifically enumerated in the Protective Order as persons authorized to review Restricted Confidential Information as well as their consultants or vendors retained pursuant to the Court's permission to effectuate class notice and to administer class or claims eligibility who are and shall remain subject to the restrictions on use and disclosure as enumerated in the Protective Order, and then solely for purposes of this Litigation only and for no other action (litigation, judicial proceedings, arbitration, mediation, or other proceeding of any type) or purpose whatsoever (including, but not limited to, business, governmental, commercial, auditing, consulting, or administrative purposes); and,

WHEREAS, the Special Master has been authorized to enter this Amended Order;

THEREFORE, the Court hereby FINDS and ORDERS the following: Upon the later of 14 days from the date this Amended Order is entered or July 23, 2024, the Pharmacy Defendants shall produce as Restricted Confidential Information, if among each Pharmacy Defendant's Previously Redacted or Withheld Information, the following for each record reflecting a dispensed prescription of at-issue Aurobindo-manufactured irbesartan (as identified by the NDC of the drug dispensed), to the extent contained in its production of Irbesartan Structured Data: (1) patient name; (2) patient mailing address; (3) patient date of birth; (4) patient e-mail address; (5) patient telephone number; and (6) identity of any third-party payor(s) associated in the data with the dispense/fill. This disclosure may require the production of the PHI of numerous individual consumers, but the Court has determined the ordered disclosure is the minimum necessary information to accomplish the stated purpose of the litigation and/or settlement. Disclosure of the names and information corresponding to these individuals shall not constitute any admission or suggestion that such individual qualifies as a member of any class certified by this Court, or an admission or suggestion that the individual is entitled to any relief. Likewise, disclosure of information (whether by name, code, abbreviation, or other potential identifier) regarding TPPs shall not constitute any admission or suggestion that that the information produced relates to a TPP plaintiff or a member of the TPP class or that the Pharmacy Defendants have access to or the obligation to produce a "key" or otherwise perform additional analysis beyond the produced information; provided that, however, both parties reserve their respective rights on this following the data's production and the parties' chance to review the data. Likewise, entry of this Order does not constitute any admission or suggestion regarding the approval of Plaintiffs' class notice plan, a proposal for which is expected to be

made after the date of this Order. Any disclosure pursuant to this Order remains subject to and governed by the Protective Order and the limitations on the use and disclosure set forth therein.

SO ORDERED, this 17th day of July, 2024

s/ Thomas I. Vanaskie

Hon. Thomas I. Vanaskie (Ret.) Special Discovery Master